

REMARKS

The pending Office Action addresses claims 1-29, all of which stand rejected. Reconsideration is respectfully requested in view of the amendments and remarks submitted herewith.

Amendments to the Claims

Applicant amends claims 1 and 10 to clarify that the mouthpiece is adapted to substantially seal an oral cavity within a patient's mouth. In a like manner, applicant amends claim 17 to recite that a substantially sealed oral cavity is formed within a patient's mouth. Support for these recitations can be found at paragraph [0025] of the published application. Applicant also amends claims 18, 23-24, and 29 to correspond to amended claim 17.

Applicant cancels claim 2, amends claim 11 to correspond to claim 10, and amends claims 9, 12, and 22 to correct minor typographical errors. Additionally, Applicant amends claims 19-21, 23-24, and 26 to correct the dependency.

No new matter is added.

Claims 1 and 3-29 are now pending.

Rejections Pursuant to 35 U.S.C. §103

The Examiner rejects claims 1-3, 5-8, 10-14, 17-20, and 24-29 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,596,983 of Zander in view of U.S. Patent No. 6,494,209 of Kulick. In particular, the Examiner argues that Zander discloses a system that "applies a negative pressure ("vacuum", col. 2, lines 55-57) through a patient[']s mouth," and "discloses the claimed invention with the exception of preventing the patient's soft tissues of the upper airway from collapsing." The Examiner thus relies on Kulick to teach a vacuum unit to create a negative pressure "which keeps the patient's tongue forward for the purpose of treating sleep apnea." Applicant disagrees with the Examiner's rejections.

Claims 1, 3, 5-8, and 10-14

Independent claims 1 and 10 are directed to a system for maintaining an open airway that includes a mouthpiece that is adapted to substantially seal an oral cavity within a patient's mouth. The mouthpiece is further adapted to be coupled to a negative pressure generator that is effective to create a negative pressure within the oral cavity to prevent the soft tissues of the upper airway from collapsing.

Neither Zander nor Kulick teach or even suggest the system of claims 1 and 10.

Zander teaches an oxygen delivery device that includes an oxygen applicator that is sealed over a patient's nose and that is used to deliver pure oxygen to the patient. The device also includes a mouthpiece having a one-way valve that opens only during gas outflow, such that none of the respired air escapes through the patient's nose and the patient receives only pure oxygen. The Examiner suggests that Zander teaches a negative pressure generator, but this is incorrect. Zander fails to teach using the negative pressure generator to prevent the patient's soft tissues of the upper airway from collapsing. Zander does not teach the application of a negative pressure to the system, but rather merely mentions using a vacuum in the context of performing a vacuum extraction on the patient after the patient has stopped breathing and *after* the mouthpiece is removed from the patient's mouth. (Column 2, lines 52-60.) Zander thus fails to teach a mouthpiece that can be coupled to a negative pressure generator, and that can create a sealed oral cavity to prevent the soft tissues of the upper airway from collapsing.

The Examiner relies on Kulick to overcome the deficiencies of Zander, arguing that it would have been obvious to use the negative pressure generator of Kulick with the device of Zander to create a negative pressure which keeps a patient's tongue forward. The mouthpiece of Zander, however, cannot be modified as suggested by the Examiner to arrive at the claimed invention. As noted above, Zander teaches a mouthpiece having a one-way valve that opens only upon gas inflow. (Column 3, lines 26-29.) Since air is free to flow into the mouth through the one-way valve, the valve will prevent a negative pressure from being generated in the oral cavity. The device of Zander therefore cannot be modified to generate a negative pressure within a substantially sealed oral cavity.

Even if the Zander device could be modified as suggested by the Examiner, Kulick does not remedy the deficiencies of Zander. Kulick teaches a mouthpiece for treating obstructive sleep disorders. While the patient is breathing, the mouthpiece holds the patient's tongue in the forward position using suction. The mouthpiece does not seal the oral cavity, much less create a negative pressure in a substantially sealed cavity within a patient's mouth. To the contrary, the mouthpiece includes breathing channels formed therein for allowing air to flow freely into and out of the patient's mouth. The only negative pressure used is applied directly to the tongue to hold the tongue within a tongue-shaped cavity in the mouthpiece. Thus, the mouthpiece does not seal the oral cavity and therefore it cannot create a negative pressure within the oral cavity, as required by claims 1 and 10.

Claims 1 and 10, as well as claims 3, 5-8, and 11-14 which depend therefrom, therefore distinguish over Zander and Kulick and represent allowable subject matter.

Claims 17-20 and 24-29

Independent claim 17 recites a method for maintaining an open airway by forming a substantially sealed oral cavity within a patient's mouth and creating a negative pressure therein to prevent the soft tissues of the upper airway from collapsing. For similar reasons discussed above, Zander does not teach or even suggest a method that creates a negative pressure in a substantially sealed oral cavity to prevent the soft tissues of the upper airway from collapsing. To the contrary, Zander does not use any type of negative pressure to prevent the soft tissues of the upper airway from collapsing. Kulick does not remedy the deficiencies of Zander, as Kulick likewise fails to teach creating a negative pressure in a substantially sealed oral cavity within a patient's mouth. Rather, Kulick teaches creating an open cavity within a patient's mouth such that the patient can still breathe through the mouthpiece. Independent claim 17, as well as claims 18-20 and 24-29 which depend therefrom, therefore distinguish over Zander and Kulick and represent allowable subject matter.

Claims 4, 9, 16, and 21-23

The Examiner rejects dependent claims 4 and 21-23 pursuant to 35 U.S.C. §103(a) as being obvious over Zander and Kulick and further in view of U.S. Patent No. 6,405,729 of Thornton. Claims 9 and 16 are also rejected pursuant to 35 U.S.C. §103(a) as being obvious over Zander and


Kulick and further in view of U.S. Publication No. 2005/0103347 of Curti. As discussed above, Zander and Kulick do not teach or even suggest a system or method that creates a negative pressure in a substantially sealed oral cavity to prevent the soft tissues of the upper airway from collapsing. Thornton and Curti do not remedy the deficiencies of Zander and Kulick. Accordingly, claims 4, 9, 16, and 21-23 distinguish over Zander and Kulick in view of Thornton and Curti and represent allowable subject matter.

Conclusion

Applicant submits that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite the prosecution of this application.

Respectfully submitted,

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